

REMARKS

Claims 1, 3-11, 13, 15-26, 29-31, 37, 40-47 and 56-68, as amended, are pending in this application for the Examiner's review and consideration. Independent claims 1, 37 and 60 have been amended to remove the term "about" from the description of the ranges of the recited components. Claim 60 has also been amended to include a limit on the amount of testosterone when it is used as the sole active agent as already recited in claims 1 and 37. Since no new matter has been introduced by any of these changes, they should all be entered at this time.

Claims 1, 3-11, 13, 15-31, 37, 40-47 and 56-68 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite using "between about" in references to concentration ranges, "from about"... "to about" in reference to effective dosage amounts, and "to about" in reference to serum levels.

Applicants again respectfully disagree with this rejection for the reasons set forth in their prior response. To advance the prosecution of the application, however, Applicants have amended the independent claims to remove the "about" qualifier and it is respectfully submitted that this overcomes the rejection. While the "about" language has been retained in the dependent claims for the amounts, it is noted as to the composition that the dependent claims fall under and within the scope of the independent claims so they are also definite for that reason while still providing some latitude for the precise amounts that are suitable for the invention. Regarding the use of the term "about" in dependent claims that describe ranges of serum levels, as Applicants have further defined the ranges of amounts that are useful in the compositions, and as the serum levels depend upon the amounts administered and the particular biological response of the patient that receives the claimed formulations, it is believed that the rejection is overcome as to these claims as well. Regarding the rejection of claim 27, that claim has been cancelled herein. Therefore, the rejection should be withdrawn in its entirety.

Claims 60 and 66-68 were rejected under the second paragraph of 35 USC 112 as being indefinite with regard to the term "polyalcohol." In response, Applicants have amended that term to "propylene glycol" as suggested in the office action such that the rejection has been overcome and should be withdrawn.

Claims 60 and 68 have been rejected under 35 U.S.C. 102(b) as allegedly being anticipated by International Patent Application Publication No. WO 2002/011768 to Carrara et al. (referred to hereafter as "Carrara").

In response, claim 60 has been amended to incorporate the language that appears in claims 1 and 37 that limit the amount of testosterone when it is used as the sole active agent. As Carrara does not disclose such amounts and as claims 1 and 37 were not rejected over Carrara, this rejection is overcome and should be withdrawn.

Claims 1, 3-8, 10, 11, 13, 15, 20, 22, 37, 40-43, 45-47, 56, 57, 60-62 and 68 have been rejected under 35 U.S.C. 102(a) and 102(e) as allegedly being anticipated by WO 02/22132 to Gray et al. (US Patent 7,030,104 is the English-language equivalent and is relied upon by the Examiner, referred to collectively as "Gray"). Also, claims 1, 3-11, 13, 15-20, 22, 26, 28, 29, 31, 37, 40-47, 56-63 and 65-68 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Gray in view of US Patent No. 6,503,894 to Dudley et al. (referred to hereafter as "Dudley"), US Patent No. 5,955,455 to Labrie et al. (referred to hereafter as "Labrie"), Catherino et al. (J. Steroid Biochem. Molec. Biol., 1995, referred to hereinafter "Catherino") and Wang et al. (The Journal of Clinical Endocrinology and Metabolism, referred to hereinafter as "Wang").

It is respectfully submitted that Gray is not an effective prior art reference against the present application. The Gray PCT application was published March 21, 2002, a date that is within one year of the filing date of Applicants' earliest provisional application, namely March 11, 2003. Furthermore, Claims 1, 37 and 60 now recite formulations that are not disclosed by Gray. As noted above, the claims are directed to formulations that contain at least one active agent of a hormone, with certain provisos, along with a delivery vehicle comprising an alkanol, a polyalcohol and a permeation enhancer of a monoalkyl ether of diethylene glycol in an amount sufficient to provide permeation enhancement of the active agent through mammalian dermal or mucosal surfaces. This invention was completed prior to the March 11, 2002 publication date of the Gray PCT application, so that all rejections based in whole or in part upon Gray should be withdrawn.

In support of the preceding statement, Applicants submit herewith a Rule 131 declaration signed by inventor Dario Carrara which establishes that the invention was made prior to the publication date of the Gray PCT application. It is respectfully submitted that the filing of this declaration is proper to antedate the Gray PCT application because (1) the effective date of Gray as prior art is less than 1 year prior to Applicant's effective filing date and (2) Gray does not claim the same patentable invention.

As all rejections have been overcome, it is believed that the entire application is now in condition for allowance, early notice of which would be appreciated. In the event that the Examiner does not agree that all claims are now allowable, a personal or telephonic interview is respectfully requested to discuss any remaining issues in an effort to expedite the eventual allowance of this application.

11/3/10

Date

Respectfully submitted,



Allan A. Fanucci

(Reg. No. 30,256)

WINSTON & STRAWN LLP

Customer No. 28765

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